smart

USER MANUAL





Eurolyser Diagnostica GmbH Bayernstrasse IIa, 5020 Salzburg, Austria

SYMBOLS AND ABBREVIATIONS

The following symbols and abbreviations are used in the product labeling and instructions for the Eurolyser laboratory photometer

Symbol/Abbreviation	Explanation
CE	Conforms with the European directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
IVD	In vitro diagnostic medical device
REF	Catalogue number/Order number
LOT	Lot number
SN	Serial number
Σ	The contents are sufficient to perform <n> number of tests</n>
	Best used by
	Temperature limitations
	Manufacturer
	Date of production
STERILE	Sterile
\triangle	Warnings and precautions, see accompanying documents
- Ing	Operator's action
i	Refer to the user's manual and follow the instructions
×	Do not dispose with household waste
ERS TC	ERS Testing Cartridge
LED	Light Emitting Diode
PC	Personal Computer
ID	Identification
HIS	Hospital Information System
LCD AC	Liquid Crystal Display
DC	Alternating Current Direct Current
RFID	Radio Frequency Identification
Tablet I	Nadio I requercy identification

Tablet I

TABLE OF CONTENTS

Introduction Intended use of the EUROLYSER smart laboratory photometer	5
About this user's manual	5
Inspecting the package contents	5
System Description	
Description of the Eurolyser smart laboratory photometer	6
How to operate the Eurolyser smart laboratory photometer Screensaver	7
Indicator lights	8
How the Eurolyser smart laboratory photometer works	8
Manufacturer's calibration	8
Touch-Screen Pictograms	
The touch-screen symbols and their functions	9
Additional symbols and special characters	9
Getting Started	
The proper placement of the smart laboratory photometer	10
Connecting the power supply Connecting the optional againment	10 10
Connecting the optional equipment How to switch on the photometer	
The automatic start-up and warm-up processes	
Configuring the photometer	12
Setting the normal values and the units, using a CRP test as demonstration	13
How to switch off the photometer	14
Testing Procedures	
Overview of the testing and measuring procedures	15
Operating safety precautions	16
Analyzing a patient's sample 17	
Viewing and processing the test results	18
Quality Control	
Choosing quality control (QC) materials	19
Handling the QC control materials	19
	19
Handling the QC control materials Frequency of QC testing Calibration	19
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration	19 20
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration	19 20 21
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration	19 20
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration Example of how to determine the manual calibration factor	19 20 21 22
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration Example of how to determine the manual calibration factor Performing an instrument calibration Interface Description Serial interface	19 20 21 22
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration Example of how to determine the manual calibration factor Performing an instrument calibration Interface Description	19 20 21 22 23
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration Example of how to determine the manual calibration factor Performing an instrument calibration Interface Description Serial interface USB interface Troubleshooting	19 20 21 22 23 24 24
Handling the QC control materials Frequency of QC testing Calibration Performing an automatic calibration Performing a manual calibration Example of how to determine the manual calibration factor Performing an instrument calibration Interface Description Serial interface USB interface	19 20 21 22 23 24

TABLE OF CONTENTS

Technical specifications	
Eurolyser smart laboratory photometer	27
Power supply	27
Options: thermo printer; barcode scanner	27
Declaration of Conformity	28
Manufacturer's Information	29

Intended use of the EUROLYSER smart laboratory photometer

The Eurolyser smart laboratory photometer is for *in vitro* diagnostic (clinical chemistry) use only.

The smart laboratory photometer is very compact and is designed as a point of care measuring instrument for the ERS (Eurolyser Reagent System). It is easy to use and provides quick, reliable and accurate results.

About this user's manual

This user's manual will guide you through the installation, operation and maintenance of your Eurolyser smart laboratory photometer. The user's manual also explains how the photometer works, describes the quality assurance system and assists you in troubleshooting any errors or problems.

We recommend that you familiarize yourself with these instructions before operating the Eurolyser smart laboratory photometer.

Some of the information in this user's manual is marked with following symbols:

Operator's action

Varnings and precautions; see accompanying documents

l Refer to the user's manual and follow the instructions

Inspecting the package contents

When unpacking the smart laboratory photometer, check the contents against the list below and examine the components for signs of shipping damage.

The smart package contains the:

- Eurolyser smart laboratory photometer
- Mains adapter, 12V DC 3A/40W
- Power cable
- User's manual

If any part of the package is missing or damaged, please report this to your supplier immediately. We recommend that you keep the original packaging, in case the instrument ever needs to be transported.

Description of the Eurolyser smart laboratory photometer

Figure 1 shows the main exterior parts of the SMART laboratory photometer (front view)

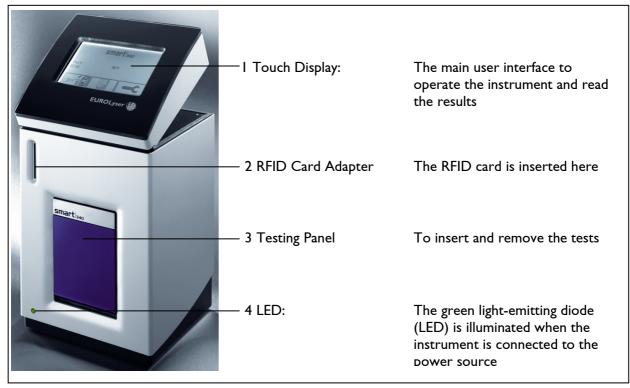


Figure I

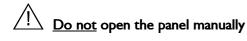


Figure 2 describes the main exterior parts of the smart laboratory photometer (rear view)

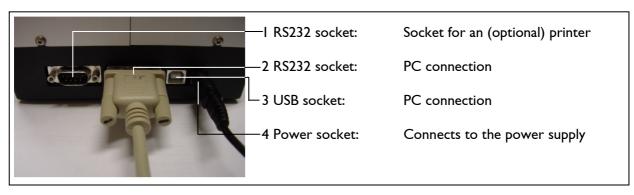


Figure 2

How to operate the Eurolyser smart laboratory photometer

The smart laboratory photometer is operated solely by means of the touch-screen. All the basic operating steps are displayed as symbols. An overview of these symbols can be found in Table 1 and Table 2. To activate a symbol, touch or tap it with a finger.

In order to perform a test, the RFID card enclosed in the testing kit must first be inserted into the laboratory photometer. This card contains all the data needed to perform the routine tests. No analysis can be started without the RFID test card!

The ERS cartridge is inserted into the slot in the front of the machine; the testing panel then opens automatically. After entering all the requested data and activating the **START** button on the touch screen, the panel closes automatically and the testing procedure begins. After the analysis is completed, the panel opens again automatically and the test cartridge can then be removed.

The panel prevents ambient light, dust, dirt and humidity from entering the laboratory photometer during the testing process and when the machine is not in use.



• <u>Do not</u> open the panel manually

• Use only your fingers to touch the screen. Do not use pens or other hard or sharp objects.

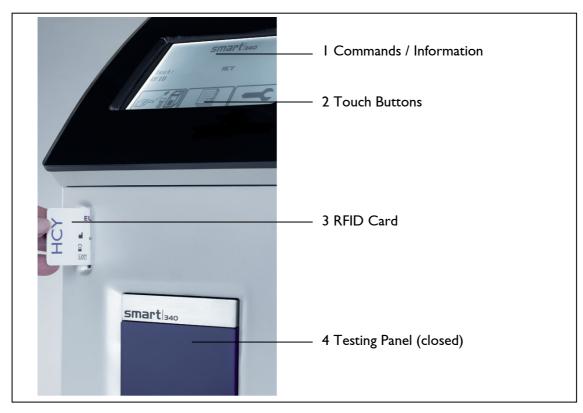


Figure 3

Screensaver

The screensaver activates after 10 minutes of idle time, dimming the touch screen. Touch the screen to re-activate it.

Indicator lights

The illuminated green diode (LED) shows that the machine is connected to the power source. The machine may be left plugged in indefinitely.

How the Eurolyser smart laboratory photometer works

The Eurolyser smart laboratory photometer is an open measuring system. That means it is able to use diverse reagents from multiple manufacturers. When tests are to be performed, the smart laboratory photometer is loaded with ERS cartridges, which are filled with reagents from the respective reagent manufacturers. The instrument can process end point tests as well as kinetic tests and – thanks to the latest LED technology – it is completely maintenance-free.

The models of smart are differentiated by the wavelengths of their built-in light sources. For example: the name "smart 546" stands for a photometer with a 546nm light source. Up to two light sources can be integrated into a photometer.

The instrument is equipped with an RFID card-reader module. RFID cards are necessary for performing any testing procedures. They are included in the testing kits from the respective test manufacturers and contain all the specific steps for the various tests, the lot data, as well as the calibration data. The instrument performs the tests automatically according to that data. Numerous types of tests can be selected and performed automatically.

The sample and the reagent are mixed automatically within the machine. The photometer unit performs the analysis with either one or two light diode(s). The absorption of light rays is measured during this process, and the measured value is then converted into the test result using mathematical methods. This result is then displayed on the touch screen. Optionally, the results can be exported to an external personal computer, an HIS, or they can be printed out using an external printer.

When the user confirms the result, the testing panel opens automatically and the ERS cartridge can then be removed and discarded. After this procedure, the instrument is ready to perform the next analysis.

Manufacturer's calibration

The Eurolyser smart laboratory photometer is manufactured according to the highest quality standards in order to yield safe and accurate testing results. Every instrument is inspected during the manufacturing process, using the EU-stipulated reference methods.

The touch screen symbols and their functions

Tapping one of these symbols on the touch screen activates the described function. Every symbol that can appear while using the instrument is described here.

Symbol	Name	Function
13~ 1	Start the analysis	Opens the menu so the user can make additional testing entries
~	Up	Selects one entry line or one value higher
\sim	Down	Selects one entry line or one value lower
	Edit	Opens an entry or value so it can be edited
 	Confirm	Confirms the input
Х	Cancel	Cancels the input
+	Delete	Deletes the last character entered
4	Enter	Confirms the input
Aa SYM	Selecting button	Selects upper / lower case and special characters
[x]	Option	Shows which element is selected
•	Start	Starts the selected operation
<i></i>	Printer	Starts printing
	Transmit	Starts data transmission
2	Chart	Displays the photometer data of the last test
	Close door	Closes the testing panel
	Results	Selects the results menu
>>	Forward	Go to the next page
<<	Backward	Go to the previous page
Ī	Recycle bin	Go to the delete menu
Y	Settings	Go to the settings menu

Table 2

Additional symbols and special characters

Additional symbols or special characters that can appear on the touch screen during operation are described here. These symbols and special characters provide additional information only and cannot be activated by touching.

Symbol	Name	Function
	Insert cartridge	Command to insert the test cartridge
	Remove cartridge	Command to remove the test cartridge

Table 3

The proper placement of the smart laboratory photometer



Place the machine on a dry, clean, stable and level surface. Make sure that the instrument has at least 10 cm of table surface and clearance on each side and that the machine can be easily disconnected from the power source. Acclimate the instrument to the ambient room temperature before operating it.



The instrument can be damaged by:

- Condensing humidity and water
- Heat and large temperature fluctuations
- Direct sunlight
- Vibrations (e.g. from centrifuges and dishwashers)
- Electromagnetic radiation (e.g. from mobile phones)

Connecting the power supply

- Connect the power cable to the power supply unit.
- Insert the plug from the power supply unit into the power socket
- on the back of the machine (Figure 4).
- Plug the power cable into the wall socket.



Always connect to the proper supply voltage. The power supply voltage must comply with the regulations cited in the technical specifications on page 27. The instrument is to be operated only using the power supply unit provided.

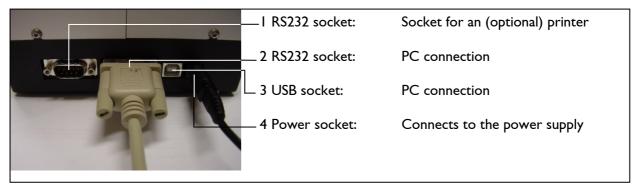


Figure 4

Connecting optional equipment

The following optional devices – which are not included in the standard delivery package – can be connected to the instrument:

- An external printer for optional test result printouts
- An external barcode scanner
- A PC for the transfer of test data into an HIS or laboratory software

We recommend the DPU-414 from SEIKO as an optional printer, as described in the "Technical specifications" section on page 27.



Connect optional equipment only when the instrument is switched off. Please note that attaching optional equipment (e.g. a printer) can increase the amount of leakage current. All optional equipment must be connected before such leakage current can be measured.



If the device is not used according to the instruction manual, then the provided levels of safety will be lowered.

How to switch ON the EUROLYSER smart laboratory photometer

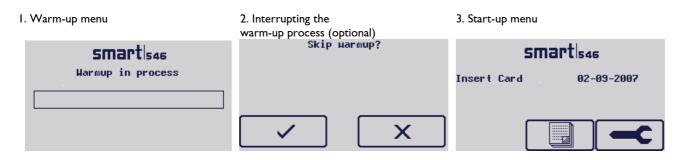


The machine is switched on by plugging the power cable into the socket. This launches the device's automatic start-up and warm-up processes. Please wait for these to be completed (approximately 15 minutes).



Do not open the testing panel manually

The automatic start-up and warm-up processes



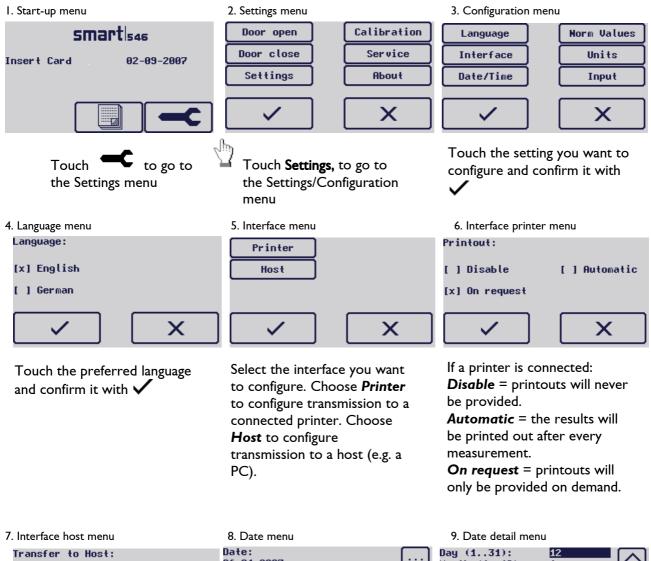
The automatic start-up procedure starts as soon as the device is connected to the power supply. The machine is warmed up to its proper working temperature in approx. 15 minutes.

If you want to interrupt the warm-up process, just touch **warm-up**. A submenu appears; press to interrupt. However, if you don't want to interrupt the process, press X

As soon as the entire progress bar turns gray and the initialization of the optical unit is completed (in a few more seconds), the start-up menu appears. The instrument is now operational.

Configuring the photometer

You can configure your Eurolyser smart laboratory photometer according to your needs before you begin using it. To go to the configuration menu, follow these steps:



Transfer to Host: [] Disable [x] On request	[] Automatic	Date: 06-01-2007 Time: 07:24:32	···	Day (131): Month (112): Year (099): Date Format:	12 1 9 DD-HH-YYYY V
 	X		X	\checkmark	X

If a host (e.g. a PC) is connected: **Disable** = data will never be transmitted to the host. **Automatic** = the results will be transmitted to the host after every measurement. **On request** = data will only be transmitted upon request. Touch ... to go to the Date detail and Time detail menus

Touch ... to go to the Date detail menu. Use \checkmark or \land to navigate on the screen

I0. Day date menu Day (131): 6 7 8 9 4 5 6 1 2 3 8	II. Date format menu I2. Tim Date Format: [X] DD-HH-YYYY [X] DD-HH-YYYY [] YYYY-HH-DD [] HH-DD-YYYY [] X	me detail menu Hour (023): 16 Hinute (059): 18 Second (059): 42 Time Format: 24 V
Touch the desired digits and confirm the selected date with	Select your preferred date format. DD = Day MM = Month YYYY = Year	Touch to go to the Time input or Time format menus. To navigate within the screen, use V and A.
I3. Time input menu Hour (023): 15 7 8 9 4 5 6 1 2 3 0	 I4. Time format menu Time Format: [x] 24 [] 12 X 	

Touch the digits to enter the time and confirm your selection with +

Select either the 12-hour time format (1 - 12 AM/PM) or the 24-hour time format (0 - 23)



To exit a menu or to cancel an input, use old X

Setting the normal values and the units, using a CRP test as demonstration

I. Configuration menu	2. Test selection menu	3. Limits menu
Language Norm Values	Test:	Louer-lim male: 9.00 Upper-lim male: 1.18 Louer-lim female: 0.00
Interface Units Date/Time Input	[x] CRP	Upper-lim female: 1.10 Louer-lim child: 0.00 Upper-lim child: 0.89
✓ X		✓ X
Touch Norm Values and confirm your selection with	Confirm the selection of CRP with 🗸	Touch to go to the numerical entry screen of the Limits menu. Use 🗸 and 🔨 to navigate

within the screen

4. Configuration menu		5. Test selection menu	6. Units selection menu
Language	Norm Values	Test:	Unit:
Interface	Units	[x] CRP	[x] mg/dl
Date/Time	Input		[] mg/l
 	X	✓ ×	✓ ×

Touch **Units** and confirm the selection with

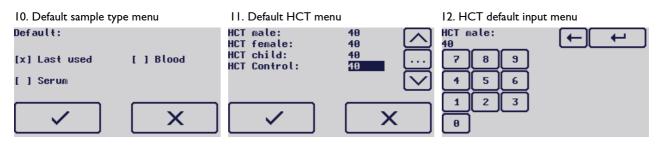
Confirm the selection CRP with \checkmark

Touch the selected unit and confirm it with \checkmark

 \triangle

This description is only an example, as the configuration of the Eurolyser laboratory photometer models varies, depending on how they are equipped.

7. Configuration menu	8. Input menu	9. Default gender menu
Language Norm Va	lues Sex	Default: >>
Interface Unit:	s Sampletype	[x] Last used [] female
Date/Time Inpu	t HCT	[]male []child
✓ X		
Touch Input and confirm the selection by pressing 🗸	e Select which values to change from the Input menu.	Select which gender is to be used as the standard default. <i>Last used</i> means that the gender last used will always be selected.



Select which type of sample should be marked by default. *Last used* means the sample type last used will be selected. Using V or A choose which HCT value to change. By pressing ... you can change the value in the HCT default input menu Enter the hematocrit value and confirm it by pressing \leftarrow . If no value is given, the analyzer uses the value 40 by default.

How to switch OFF the analyzer

Д.

Completely turning off the instrument can only be accomplished by disconnecting it from the power supply. It is not necessary to switch the analyser off every day. When the instrument is in start screen mode, the "power safe" function dims the screen after it has been idle for 10 minutes. Touching the screen will re-illuminate it to its customary level of brightness.

Overview of the testing and measuring procedures

Allow the ERS test cartridge to come to room temperature before use. If the smart laboratory photometer has been disconnected from the power supply, plug it in soon enough for it to be at the proper operating temperature when it is needed.

How to run a control test, if necessary:

- Insert the RFID card from the testing kit into the slot on the front of the machine
- Prepare the control serum according to the instructions on the control package insert
- Enter the lot number instead of the patient data
- Prepare the test just like a patient sample and start the analysis
- The result is displayed
- Record the result according to your laboratory's quality guidelines
- The result will be saved in the instrument's memory just like a patient's results
- Verify that the result lies within the mandatory limits for the control material (according to the control material's package insert)

To analyze a patient sample:

- Insert the RFID card from the testing kit into the machine
- Prepare a test cartridge and a patient sample according to the instructions on the testing kit insert
- Enter the required patient data
- Insert the test cartridge into the analyzer and start the analysis
- The result will be displayed
- The result will be saved in the instrument's memory
- Export the result to an (optional) external computer, or print the result with an (optional) external printer

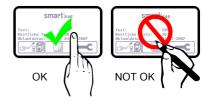
Be sure to follow the detailed instructions for the analysis processes that are provided in the following sections and to comply with the information provided on the package insert enclosed with each testing kit.

TESTING PROCEDURES

Operating safety precautions:

When operating the laboratory photometer:

- \triangle
- Use only your fingertip to operate the touch screen. Do not use pens or any other objects that may scratch or damage the screen.
- The testing panel opens and closes automatically. Do <u>not</u> try to open or close the panel manually.
- The panel protects the analysis system from dust, dirt and humidity. Empty the panel's cartridge chamber after every analysis and keep it closed when the machine is not in use.
- If an error message appears on the screen during an analysis, please consult the "Troubleshooting" section on page 25.



When handling a test cartridge:

- Do not use test cartridges after their expiration date, or when the test cartridges have not been stored in accordance with the regulations.
- Do not use the test cartridge if the packaging is damaged or if fluids have leaked.
- The test cartridge must reach room temperature (15-30°C, 59-86°F) before use.
- Never allow a test cartridge to remain at room temperature for a long period, as this may affect its stability and lead to inaccurate test results
- Use gloves when handling and disposing of the test cartridges, patient samples and sample collection equipment, because they pose a potential biohazard
- Do not re-use the test cartridges
- Use only test cartridges that have been approved or specified by the manufacturer
- Test cartridges that have been approved by the manufacturer are listed in Eurolyser Diagnostica's product list. This product list can be obtained from the Downloads page at www.eurolyser.com.

See the package insert that comes with all test cartridges suitable for use with the Eurolyser smart laboratory photometer and follow all instructions regarding:

- the proper temperature a cartridge must have before a test is performed
- the exact amount of the sample volume
- the regulations for the proper storage of the test cartridges
- the stability of the test cartridges and their expiration date
- the sequence of the testing procedures

i

TESTING PROCEDURES

Analyzing a patient's sample





Take the provided RFID card out of the testing kit package and insert it into the analyzer The analyser automatically reads the card, displays the type of test, number of tests, the expiry date and lot number.

Touch The panel opens automatically and the input menu appears.

Touch ... The ABC menu appears. To navigate within the input menu, use \checkmark and \land



To leave a menu or to cancel an entry, touch ${\sf X}$

-

4. ABC menu				
Name: M				ĺ
Â	В	C	D	ĺ
Ē	Г	[]	<u> </u>	ſ

ய	டீ	டீ	ய	டீ	ഥ	Ľ
H	Ι	IJ	K	Ŀ	H	
0	P	Q	R	S	Т	
V	۳	X	Y	Z	\Box	(A) SY



Enter the name and confirm the entry with ← . To delete an incorrect entry, use ← 5. Numeral menu



Enter the patient ID and confirm it with \leftarrow . To delete an incorrect entry, use \leftarrow ←

6. Input menu – Gender / Control



Touch Male, Female, Child or Control and confirm the selection with

TESTING PROCEDURES

Analyzing a patient's sample (cont'o	<u>1)</u>	
7. Sample type menu	8. Hematocrit menu (for all tests)	9. Start analysis menu
Sampletype: [x] Serum [] Blood 	Hematocrit: 40 7 8 9 4 5 6 1 2 3 0	Insert Cartridge
Touch Serum or Blood and confirm the selection with ✓	Enter the hematocrit value and confirm it with ← . If you do not enter a value, the analyzer uses a default value of 40	Fully insert the test cartridge into the analyzer. Touch The panel closes and the test is performed automatically.
The instrument displays the followi	ng information during the automatic t	testing process (no user input necessary)
10. Mixing Heasurement	. Incubating Heasurement	12. Measuring Heasurement
Minima di ses	Toront all from the second	Managemine E7 and

Measurement	Measurement	Measurement
Mixing 1 sec	Incubating 4 sec	Measuring 57 sec

- Be sure to handle the test cartridge according the instructions on the package insert.
- \cdot Be sure the test cartridge is properly sealed before you insert it into the analyzer.
- Be sure the test cartridge is fully inserted into the proper opening in the analyzer.
 - Use ONLY manufacturer-approved test cartridges, otherwise serious damage to the smart photometer or inaccurate test results may occur
- Do not attempt to open or close the panel manually.

Viewing and processing the test results

The smart laboratory photometer can store up to 100 patient and control results in its memory. When this capacity is exceeded, the oldest results are deleted in chronological order. The following parameters are saved from each test:





The result is shown. Touch to print it out. Touch To export it to an LIS or PC, or touch display the photometric data. Touch \checkmark to close the menu and end the test. The analyser automatically opens the testing panel. Remove the test cartridge and discard it. Touch \triangleq to close the panel. The main menu appears.

Touch to go to the overall result menu.

To scroll through the menu, touch >> or <<. Touch to print the result; touch to send it electronically. Touch to delete the result. You can return to the main menu with \checkmark

smart use

QUALITY CONTROL

A quality control program should be performed on a regular basis to verify the Eurolyser smart laboratory photometer is working properly and providing reliable results. Data integrity can only be assured when controls and GCLP practices are used routinely. The frequency of performing QC differs from laboratory to laboratory; please comply with your national quality control regulations.

Choosing quality control (QC) materials

The authorized manufacturers of the smart test cartridges also supply control materials. These control kits contain control materials, which allow you to assess the measuring accuracy of the instrument.

Ensure the measuring methods are compatible with the Eurolyser smart laboratory photometer before using QC kits from other suppliers.

The measuring methods are listed on the test cartridge's package insert.

Handling the QC control materials



Consult the package insert that comes with each control kit for detailed instructions on the storage and handling of the control materials.

Follow the instructions in the "Testing procedures/Analyzing a patient's sample" sections (pp. 15-18) on how to properly perform a control test. The measured values must be within the range of target values specified on the control vial label or in the control package insert. If the control results fall within the specified range, the testing of patient samples may begin.

If one or more controls tested outside the specified control range:

- Verify that the control materials have been stored according to the directions and that the expiration date has not passed
- Verify that the handling and testing procedures were performed according to the directions on the package insert
- Repeat the control test, using a new control from the same lot

If one or more control results are still outside the specified range;

- Perform a test using a control from a new lot

If the above instructions have been followed, but the control results are still not within the permitted range, contact your local Eurolyser smart laboratory photometer supplier for assistance before proceeding with tests on any patient samples.

Frequency of QC testing:

Control testing is recommended when:

- a new shipment of testing kits is about to be used
- a new lot is about to be used
- if it's possible that the test cartridges have not been properly stored
- if an unexpected patient result is obtained
- when new personnel is being trained to use the equipment
- if local regulations require more frequent control testing than described above, then the number of control tests performed must comply with these regulations

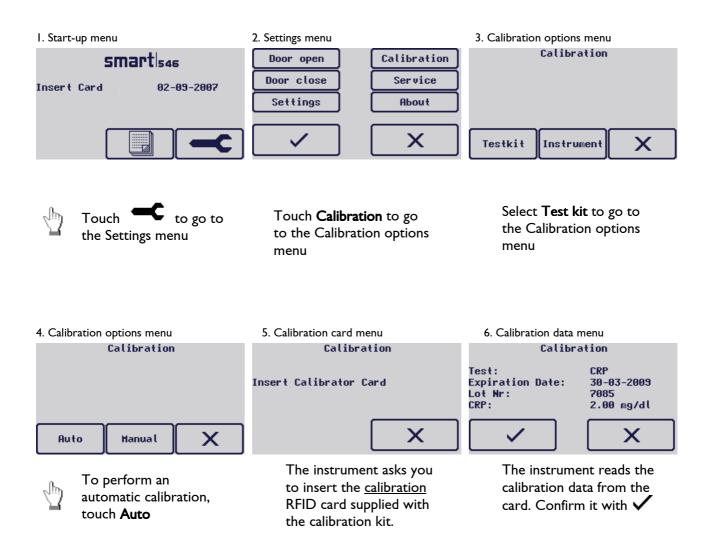
If control testing with the proper control materials produces results that are outside the prescribed ranges, then the instrument must be calibrated.

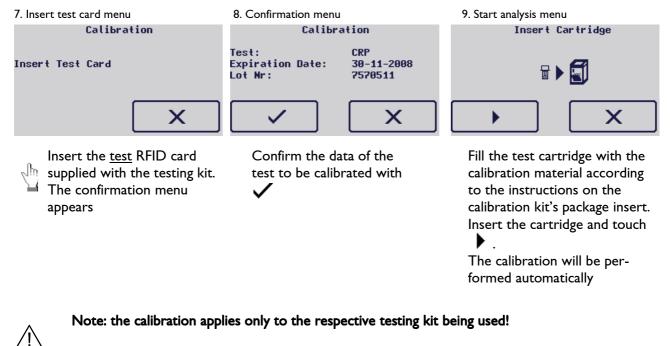


The instrument is set to perform either an automatic calibration using a calibration kit or a manual calibration by entering a factor

You'll need the proper calibration kit to perform an automatic calibration. The kits differ depending on the type of test being performed. Please follow the instructions in the calibration kit's package insert.

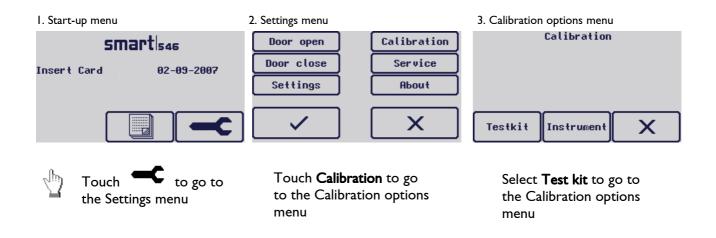
Performing an automatic calibration

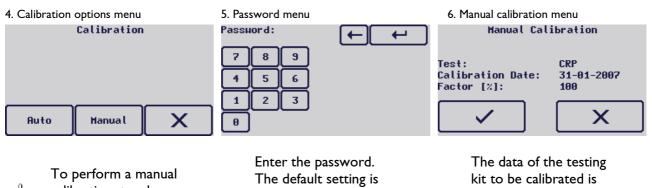




If the above instructions have been followed, but the control results are still not within the permitted range, contact your local Eurolyser smart laboratory photometer supplier for assistance before performing the next test on a patient's sample.

Performing a manual calibration







calibration, touch Manual

3010. Confirm it with 🕶 displayed. Confirm it with 🗸

7. Detail entry menu		
Factor [%]: Day (131):	<u>100</u> 31	
Month (112): Year (099):	1 2	·]
rear (033).	ŕ	
		× I

Change the factor according to the difference from the target value of a control serum. Confirm it with \checkmark

Example of how to determine the manual calibration factor



The calibration factor can be determined empirically by analysing a control serum:

The target value of the control serum is e.g.:

3.6mg/l - 6.4mg/l

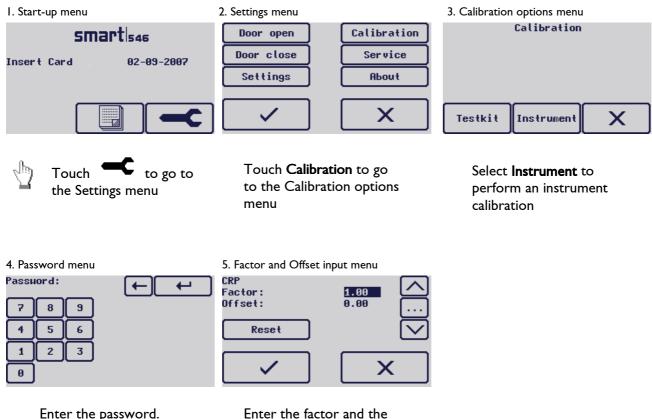
The measured value of the control serum is e.g.: 8.00 mg/l In this case, the instrument produces a result that is too high, so that means that the calibration

factor must be decreased (the default value is 100). Decrease the calibration factor by 5 units.

The default value is 100, so set the new factor at 95 and repeat the measurement of the control serum.

If the result is still outside the control serum's specified range, then decrease the factor by another 5 units and repeat the procedure.

Performing an instrument calibration



Enter the password. The default setting is 3010. Confirm it with + Enter the factor and the offset accordingly. Confirm them with 🗸

SERIAL INTERFACE:

Interface signals

Pin	Signal
1	
1 2	TxD
3	RxD
4	
5 6	GND
б	
7	
8	
9	

Interface parameters

Parameter	Value
Baud rate	9600
Data bits	8
Parity	None
Stop bits	1

Data format

Data is transmitted in blocks of data sets.

One data set contains the data from one analysis.

Data sets consist of data fields.

A data field consists of an identifier (7 characters) and its respective value or text.

Data fields are concluded with one carriage return and line feed.

Data sets are concluded with three carriage returns and line feeds.

Data Fields

Identifier	Format	Example	Remarks
Name:	Text	Name: John Doe	
ID:	Text	ID: 1234	
Sex:	Male/Female/Child/Control	Sex: Male	
Sample:	Serum/Blood	Sample:Blood	Optional
HCT:	Value	HCT: 40	Optional
Testname:	Value and unit	CRP: 2.48 mg/dl	
Range:	Value - Value	Range: 0.00 - 1.00	Optional
Time:	hh:mm	Time: 14:44	
Date:	dd-mm-yyyy	Date: 08-02-2007	

USB Interface:

The USB interface emulates the serial interface

Error messages and possible causes

Error message	Cause	Correction
- Invalid card	A wrong, defective or expired RFID card	Use a new testing kit
	A defective RFID module	Contact your dealer
- No results	No test results are stored	Perform the test
- Invalid calibration	The calibration values are outside the prescribed range.	Repeat the calibration with a new testing kit or a new calibrator.
	An error occurred during calibration.	If the problem recurs, contact your dealer.
- Tests expired	The test cartridge has passed its expiration date.	Use a cartridge from a new testing kit that has not expired.
- Calibration required	The calibration interval has been exceeded	Perform a new calibration
- Door blocked	The test cartridge is blocking the testing panel because the cartridge has not been inserted completely or the cuvette has not been capped firmly enough.	Reposition the test cartridge or tighten the cap on the cuvette.
- Wrong cap Missing cap Missing cartridge	The wrong ERS cap is being used or the ERS cap is missing or the cartridge is missing	Use the correct ERS cartridge and cap
- Latch blocked	The test cartridge blocks the latch because the wrong ERS cap is being used.	Use the correct ERS cartridge and cap
- Measurement overflow	The photometric measurement value is outside the measuring range (e.g. if a cold cartridge has been used)	Repeat the test using a new cartridge
- Blank value error	The photometric measurement value is outside the measuring range (without the cartridge)	Repeat the test after restarting the machine
- Temperature error	The temperature is outside the range	Repeat the test after restarting the machine
- Wrong sample type?	The wrong sample type has possibly been selected	Select the correct sample type
- Linearity error	The reaction to a kinetic test is not linear (e.g. if a cold cartridge has been used)	Repeat the test using a new sample and a new cartridge

ERROR INFORMATION AND TROUBLESHOOTING

Service information

If the problem persists after the corrective actions are taken, contact your local smart laboratory photometer dealer for technical assistance.

Before asking for assistance, please have the following information ready:

- the serial number of your smart laboratory photometer
- the test type
- the test lot number
- the control lot number
- the control results obtained so far
- a description of the problem, including any of the smart's error messages

Eurolyser smart laboratory photometer

Photometer resolution Reproducibility	0.0001 ABS <1.5% CV at 1 OD 0.1000 – 3.0000 OD better than +/- 1.5% and +/- 0.01 OD		
Linearity Temperature control			
·	·	Electrical temperature control of the photometer unit to $37^{\circ}C + 2^{\circ}C$	
Display	Standard LCD display with back light and integrated touch panel		
Buffer battery	BR2032		
Fuse	2.5 amperes, self-healing		
Dimensions	260 x 145 x 140 cm (H x B x T)		
Weight	3.5 kg (unpackaged)		
Communications interface	RS232, USB		
Tolerance conditions:	Work space: Transport/Storage:	15 - 28°C; relative humidity: 10 – 90% 0 - 50°C; relative humidity: 5 – 95%	
Work surface:	A dry, clean, level surface. Avoid direct sunlight		

Power supply

		Alternatively	
Manufacturer	Mascot	Globtek	
Туре	9921	GTM21097-5012	
Mains adapter	A separate AC to DC mains adapter with double insulation		
Input	100-230V AC, 50-60 Hz	90-264V AC, 47-63 Hz	
Output	12 V DC, 3A	12V DC, 4.17A	
Power usage	Max. 30 VA	Max. 30 VA	

Options

Thermo printer Interface Mains adapter	Seiko DPU-414 Serial 100-240 VAC
Barcode reader (scanner)	Datalogic Touch65
Reading area	63mm
Max. resolution	0.10mm (4mils)
Mains adapter	100-240 VAC

IP rating

IP – Safety Class III

Declaration of conformity with IVD directives

The Eurolyser SMART laboratory photometer is in compliance with all provisions in the directive 98/79/EC on In Vitro Diagnostic medical technology products and is CE-marked as conforming to standards.

Safety standards

The Eurolyser SMART laboratory photometer has been tested and conforms to the safety standards IEC/EN 61010-1, IEC/EN 61010-2081 and IEC/EN 61010-2-101, as well as to the EMC standard IEC/EN 61326

MANUFACTURER DATA



EUROLYSER DIAGNOSTICA GmbH

Bayernstrasse 11a

5020 Salzburg

AUSTRIA

Tel: +43 662 432100

Fax: +43 662 432100-50

www.eurolyser.com

Contact: Gerhard Bonecker, MBA